Digital Medicine Innovation Cycle Checklist

Solution Name: _____ ☐ Not Done ☐ + Partial ☐ √ Completed **Date:** _____

IML	Overall Description	Clinical	Business	Regulatory	Technology
1. Need	Insights into unmet medical needs and available solutions	☐ Unmet need statement ☐ Disease state characterization	☐ Needs screening & selection ☐ Existing solutions characterization	☐ Regulatory Familiarization	☐ State-of-the-Art Summary
2. Idea	Potential solution to unmet need described, evaluated, and selected	☐ Workflow Scenario ☐ Updated need statement ☐ Envisioned benefit statement ☐ Feedback from 5+ clinical stakeholders	☐ Competitive landscape ☐ Envisioned Value Proposition ☐ Key stakeholders identified ☐ Reimbursement familiarization	☐ Medical device determination ☐ Comparables identified	☐ Idea screening and selection ☐ System and module requirement specification ☐ Interface mock-upsl ☐ Institutional IP disclosure
3. Proof of Concept (PoC)	Key component concepts validated in models and value proposition tested	☐ Feedback from clinical stakeholders in 5+ settings ☐ Updated need statement and workflow scenario ☐ Target outcomes	☐ Competing solutions characterization ☐ Preliminary value proposition ☐ Path-to-Payment plan ☐ Stakeholder map ☐ Business protection model	☐ Preliminary regulatory classification and pathway ☐ Preliminary indications for use ☐ Preliminary risk and hazard analysis	☐ Preliminary system & software architecture ☐ Key module PoC prototypes ☐ Demonstration results ☐ Updated institutional IP disclosure ☐ Key in-sourcing requirements
4. Proof of Feasibility (PoF)	Feasibility of whole solution demonstrated in models and in feedback from stakeholders	☐ Feedback from clinical stakeholders in 20+ settings ☐ Updated need statement and Use Case scenario/ workflow ☐ Updated target outcomes	☐ Feedback from 5+ economic buyers ☐ Preliminary business model ☐ Development plan ☐ Key relationships identified ☐ Business advisory board ☐ Secure Access to Core IP	☐ Draft essential requirements checklist ☐ Draft product claims ☐ Draft instructions for use ☐ Institutional approval request(s) ☐ Cyber security plan ☐ Submission pathway defined	☐ Product Requirement Document (PRD ☐ Software & hardware architecture ☐ "Works Like" prototypes ☐ Essential experiment results ☐ Risk mitigation & interoperability plan ☐ Provisional IP filing & initial FTO review ☐ Key in-sourcing plans

5. Proof of Value (POV)	The potential of the solution to work and create value for stakeholders is demonstrated	☐ Feedback from 100+ users ☐ Feedback from 5+ KOLs ☐ Medical advisory board ☐ Clinical pilot ☐ Clinical trial endpoints	☐ Incorporation & Founder's agreement ☐ Key management team committed ☐ Investor ready business plan ☐ Feedback from 10+ economic buyers ☐ Initial seed investment ☐ Key relationships formalized	☐ Essential requirements checklist ☐ Application to regulatory authority submitted ☐ Clinical Investigation approval(s) ☐ Protected Health Information (ePHI) plans	☐ "Works Like, Looks Like" prototypes ☐ Essential technical experiments results ☐ Interoperability validation ☐ IP search report ☐ Key in-sourcing requirements committed ☐ cGMP compliant pilot medical software & production enviroment(s)
6. Initial Clinical Trials	Regulated production of prototypes and collection of clinical and economic data	☐ Endpoints achieved in Feasibility clinical trials ☐ Demo feedback from 20+ users ☐ Peer reviewed publication(s) submitted	☐ Value quantification ☐ Feedback from 20+ economic buyers ☐ 1st Institutional Investment	☐ GDPR/HIPAA compliance ☐ Security and vulnerability certifications ☐ Data requirements confirmation ☐ Pre-submission sent	☐ Updated specification & experimental validation ☐ All in-sourcing requirements achieved ☐ Full IP application
7. Validtion of Solution (VoS)	The solution is shown to be effective and its value to all stakeholders is validated	☐ Endpoints achieved in pivotal clinical trials ☐ Peer reviewed publication(s) accepted	☐ Purchasing intent from 10+ buyers ☐ Second round of institutional investment	☐ Submission of technical file to regulatory body	☐ Quality assured process validation (cGMP) ☐ Updated specification & experimental validation
8. Approval & Launch (A&L)	Institutional and regulatory approval received and sales launch	☐ Training materials & Support established ☐ Specialty medical groups review in place	☐ Initial sales ☐ Regionalization plans	☐ Registration and listing ☐ CMS/Public Coverage and CPT/DRG code determination	☐ Finalized cGMP production environment ☐ Regionalization requirements
9. Clinical Use (Use)	The solution is used successfully in day-to-day clinical practice	☐ Included in local practice guidelines ☐ Peer reviewed publications	☐ Profitable sales ☐ New markets launched	☐ Monitoring/ inspections	☐ Regionalization implemented ☐ Improvement plan
10. Standard of Care (SoC)	The solution is recognized as the standard of care	☐ Recommended practice by medical specialty	☐ Dominant market share ☐ Health economics study	☐ Product Obsolescence Plan	☐ Component Obsolescence Plan